

§ 20.87

21 CFR Ch. I (4–1–02 Edition)

of this chapter or court proceedings, where data or information are relevant. The Food and Drug Administration will take appropriate measures, or request that appropriate measures be taken, to reduce disclosure to the minimum necessary under the circumstances.

[42 FR 15616, Mar. 22, 1977, as amended at 60 FR 38633, July 27, 1995]

§ 20.87 Disclosure to Congress.

(a) All records of the Food and Drug Administration shall be disclosed to Congress upon an authorized request.

(b) An authorized request for Food and Drug Administration records by Congress shall be made by the chairman of a committee or subcommittee of Congress acting pursuant to committee business.

(c) An individual member of Congress who requests a record for his own use or on behalf of any constituent shall be subject to the same rules in this part that apply to any other member of the public.

[42 FR 15616, Mar. 22, 1977, as amended at 59 FR 536, Jan. 5, 1994]

§ 20.88 Communications with State and local government officials.

(a) A State or local government official commissioned by the Food and Drug Administration pursuant to 21 U.S.C. 372(a) shall have the same status with respect to disclosure of Food and Drug Administration records as any special government employee.

(b) Communications with State and local government officials with respect to law enforcement activities undertaken pursuant to a contract between the Food and Drug Administration and such officials shall be subject to the rules for public disclosure established in § 20.64.

(c) Communications with State and local government officials who are not commissioned pursuant to 21 U.S.C. 372(a) or under a contract to perform law enforcement activities shall have the same status as communications with any member of the public, except that:

(1) Investigatory records compiled for law enforcement purposes by State and local government officials who perform

counterpart functions to the Food and Drug Administration at the State and local level, and trade secrets and confidential commercial or financial information obtained by such officials, which are voluntarily disclosed to the Food and Drug Administration as part of cooperative law enforcement and regulatory efforts, shall be exempt from public disclosure to the same extent to which the records would be so exempt pursuant to §§ 20.61 and 20.64, as if they had been prepared by or submitted directly to Food and Drug Administration employees, except that investigatory records shall be exempt from disclosure for a longer period of time if the State or local government officials so require as a condition of their furnishing the information to the Food and Drug Administration.

(2) Disclosure of investigatory records compiled for law enforcement purposes by the Food and Drug Administration to State and local government officials who perform counterpart functions to the Food and Drug Administration at the State and local level as part of cooperative law enforcement efforts does not invoke the rule established in § 20.21 that such records shall be made available for disclosure to all members of the public.

(d)(1) The Commissioner of Food and Drugs, or any other officer or employee of the Food and Drug Administration whom the Commissioner may designate to act on his or her behalf for the purpose, may authorize the disclosure of confidential commercial information submitted to the Food and Drug Administration, or incorporated into agency-prepared records, to State government officials as part of cooperative law enforcement or regulatory efforts, provided that:

(i) The State government agency has provided both a written statement establishing its authority to protect confidential commercial information from public disclosure and a written commitment not to disclose any such information provided without the written permission of the sponsor or written confirmation by the Food and Drug Administration that the information no longer has confidential status; and

(ii) The Commissioner of Food and Drugs or the Commissioner's designee